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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,540	11/20/2003	Ron L. Hale	00063.01R	3439

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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	**PAPER NUMBER**
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/719,540	HALE ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *21-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-24 are pending. Claims 21-23 were withdrawn from consideration because these were drawn to non-elected subject matter. Claims 1-20 and 24 are under consideration in the instant office action. Receipt and consideration of Applicants' amended claims and remarks/arguments, submitted on November 30, 2006, is acknowledged.

Election/Restrictions

Applicant's election without traverse of Group I in the reply filed on November 30, 2006 is acknowledged.

Specification

The objection to the specification for the incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent **is maintained**. The essential material incorporated by reference is the identification of what constitutes suitable prodrugs of loxapine, for example, by incorporation by reference of (1) Krise et al., *J Pharm Sci.* **1999**, *88* pp 922 and 928 and (2) *J Med Chem.* **1999,** 42, pp 3094.

The objection of claims 1, 11, 17, and 18 because of the informalities cited on page 5 of the office action mailed on June 2, 2006 **is withdrawn** per Applicants' claim amendments correcting said informalities.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for

patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claims 1-3 and 10-15 under 35 U.S.C. 102(e) as being anticipated by Dehaven et al. (WO 02/060870; IDS) **is maintained** for the reasons of record set forth on pages 5-6 of the office action mailed on June 2, 2006.

Response to Arguments

Applicant's arguments filed November 30, 2006 have been fully considered but they are not persuasive. Applicants have traversed the instant rejection based on the following arguments: (1) the cited prior art does not anticipate the cited claims because it does not disclose the administration of loxapine to treat pain (i.e. as an analgesic); (2) the cited reference repeatedly states that N-desmethyl analogs of clozapine and loxapine constitute preferred embodiments; (3) the Applicants perceive loxapine's lower binding ability to the delta-opioid receptor as representing a negative control and not a teaching of its ability to treat pain by binding to said receptor; (4) and Dehaven did not use loxapine in *in vivo* studies.

The Examiner respectfully disagrees with Applicants' reading of the reference and conclusion that Dehaven does not teach a method of treating pain by administration of loxapine. Applicants are reminded that a reference's preferred embodiments or other preferences do not constitute a teaching away, but are merely a statement of a preference, nothing more and nothing less. Applicants had cited the data in Table 1 as evidence that Dehaven allegedly taught away from the use of loxapine as disclosing the same method of treating pain claimed by Applicants. This is an incorrect reading of the disclosures of the prior art and Applicants' claims. The data in

Table 1 clearly demonstrates that loxapine binds to the delta opioid receptor (i.e. that in has utility in the treatment of pain). Furthermore, Applicants' claims only require the administration of loxapine and do not require treatment of pain to mean that the administered drug has a specific binding to the delta opioid receptor. Any measurable binding to the delta opioid receptor reads on the treatment of pain. Applicants' specification does not redefine the treatment of pain to require any specific binding to or percent inhibition of the human delta opioid receptor as characterizing said treatment. The fact that Dehaven did not utilize loxapine in *in vivo* studies is not a teaching away from the treatment of pain by administration of loxapine. Finally, Applicants are directed to pg. 23, lines 13-17, wherein Dehaven clearly states, "formula (I) set forth herein indicates that phenothiazines, thioxanthenes, and related tricyclic structures also have delta opioid receptor agonist activity, ***and also fall within the scope of the present invention***." The Examiner concludes that the disclosures of Dehaven do anticipate the cited claims. Therefore, this rejection remains proper.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1-9 and 24 under 35 U.S.C. 103(a) as being unpatentable over Burns et al. (U.S. Patent No. 5,284,133) **is maintained** for the reasons of record set forth on pages 7-10 of the office action mailed on June 2, 2006.

The rejection of claims 10-15 under 35 U.S.C. 103(a) as being unpatentable over Burns et al. (U.S. Patent No. 5,284,133) as applied to claims 1-9 and 24 above, and further in view of Drug Information Handbook, 2nd edition (Lexi-Comp, Inc.: Cleveland, 1994-1995, pp 554-555) ("DIH") **is maintained** for the reasons of record set forth on pages 11-12 of the office action mailed on June 2, 2006.

The rejection of claims 16-17 and 19-20 under 35 U.S.C. 103(a) as being unpatentable over Burns et al. (U.S. Patent No. 5,284,133) as applied above to claims 1-15 and 24 and further in view of Nguyen et al. (U.S. Patent No. 7,040,314) **is maintained** for the reasons of record set forth on pages 12-15 of the office action mailed on June 2, 2006.

The rejection of claims 16-18 under 35 U.S.C. 103(a) as being unpatentable over Burns et al. (U.S. Patent No. 5,284,133) as applied to claims 1-9 and 24 above, and further in view of Rabinowitz et al. (US 2004/0009128) **is maintained** for the reasons of record set forth on pages 15-17 of the office action mailed on June 2, 2006.

Response to Arguments

Applicant's arguments filed November 30, 2006 have been fully considered but they are not persuasive. Applicants' traversal of the above rejections under 35 U.S.C. §103(a) are all based on the allegation that it was inappropriate to read the teachings of Burns to mean that loxapine hydrochloride was a known headache analgesic. The Examiner respectfully disagrees that Burns does not teach the utility of loxapine hydrochloride as a headache analgesic and that the interpretation of the teachings of Burns set forth in the office action mailed on June 2, 2006 is incorrect. The Examiner has noted Applicants data. No unexpected or surprising results were demonstrated. Therefore, the aforementioned rejections in the instant office action under 35 U.S.C. §103(a) remain proper.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection on the ground of nonstatutory obviousness-type double patenting of claims 1, 16-17, and 19 as being unpatentable over claims 7, 9, 10, 12, and 13 of U.S. Patent No. 6,716,416 (USPN '416) **is maintained** for the reasons of record set forth on pages 17-18 of the office action mailed on June 2, 2006.

The provisional rejections on the ground of nonstatutory obviousness-type double patenting of claims 1 and 16-20 (claim 20, only with copending '877) as being unpatentable over (1) claims 12, 15, 16, and 18 of copending Application No. 10/653,876 (copending '876) and (2) claims 1 and 7-9 of copending Application No. 10/633,877 (copending '877) **are maintained** for the reasons of record set forth on pages 18-19 of the office action mailed on June 2, 2006.

Response to Arguments

Applicant's arguments filed November 30, 2006 have been fully considered but they are not persuasive. Applicants' have not provided any substantive arguments traversing the above-cited non-provisional and provisional obviousness-type double patenting rejections. These rejections are maintained at this time.

Conclusion

Claims 1-20 and 24 are rejected. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571)

272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0664. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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